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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

MOORE, W

ART UNIT	PAPER NUMBER
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1652

DATE MAILED:

09/05/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.

09/185,663

Applicant(s)

BANG ET AL.

Examiner

William W. Moore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2000.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-98 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-97 is/are allowed.
- 6) ☒ Claim(s) 98 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) \_\_\_\_\_.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

### Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

## DETAILED ACTION

### *Specification*

13. Claims 93-98 submitted with Paper No. 7, Applicants' Amendment B filed April 14, 2000, have been entered. The amendment submitted with Paper No. 7 bridging pages 6-  
5 7 of the specification has been entered and appropriately corrects an obvious typographical error. It is agreed that it adds no new matter. Claims 93-97 submitted with Paper No. 7 likewise adds no new matter. Claim 98, however, adds new matter as discussed separately hereinbelow. Each of claims 93-97 defines a scope intermediate between an independent claim of the patent from which it ultimately depends and one or more patented claims that  
10 also depend from the same independent claim of the patent. Each of claims 93-97 could have been presented and prosecuted in application Serial No. 06/699,967 pursuant to the restriction requirement therein, where the independent claims of the patent permit the preparation of a DNA that exists within the human Protein C-encoding DNAs of claims 1, 68, and 69. A failure to present claims such as claims 93-97 more particularly describing  
15 intermediate subject matters, e.g., the human Protein C zymogen contemplated in claim 1 and clause (iii) of claim 69 which is now explicitly stated in claims 94 and 97, might be considered an error in overlooking available, patentable, embodiments. Claims 93-97 are allowable over the prior art considered in the parent application and reconsidered herein because, like claims 83-92 submitted with Paper No. 2, each requires that a constructed  
20 DNA compound comprise a nucleotide sequence encoding the entire amino acid sequence of the human Protein C light chain a encoded by the cDNA Applicants discovered. While Foster et al. and Long et al. teach methods for identifying a generic Protein C-encoding cDNA present in a cDNA library generated enzymatically from bovine and human liver mRNA transcripts, neither provide any basis for predicting the thirteen unknown amino  
25 acids corresponding to the remainder of the light chain amino acid sequence.

*Surrender of Original Patent, Duty of Disclosure, & Correction of Patent*

14. Applicants are again reminded that the original patent must be surrendered or an affidavit submitted averring its irretrievable loss or misplacement prior to allowance of the instant application. While the amendment to the specification submitted with Paper No. 7  
5 corrects an error not corrected in the issued patent, Applicants are again reminded that the several corrections made in the Certificate of Correction to U.S. Patent No. 4,775,624 issued January 8, 1991, must also be entered in this patent specification. See MPEP §§1411.01 & 1416. Applicants are again reminded of the continuing obligation under 37 CFR 1.56 to timely appraise the Office of any litigation information, or other  
10 prior or concurrent proceeding, involving Patent No. 4,775,624, material to patentability of the claims under consideration in this reissue application. This obligation rests with each individual associated with filing and prosecution of this application for reissue. See MPEP §§1404, 1442.01 & 1442.04.

*Sequence Rules Compliance is Optional*

15 15. While compliance with 37 CFR §1.821 is not required in the instant application because it is, in effect, a continuation of an application filed before the inception of the Sequence Rules, Applicants are again reminded that **full** compliance, rather than partial compliance, with the Sequence Rules is necessary if Applicants desire that a computer-readable, thus computer-searchable, Sequence Listing be available to the USPTO and to  
20 the public in the USPTO nucleotide and amino acid sequence files with which to identify the instant application. An amended CRF diskette and amended printed copy of the Sequence Listing should also include all sequences of ten or more nucleotides, and all sequences of four or more amino acids, disclosed in the specification and claims, each with a sequence designation, to bring the application into compliance with 37 CFR §1.821(a).  
25 An amended CRF diskette and amended paper copy of the Sequence Listing may be

submitted at any time during the prosecution of the instant application to bring it into full compliance with the Sequence Rules and should be accompanied by a statement of identity of printed and computer readable forms as set forth in 37 CFR §1.821(f).

*New Matter Objection and Claim Rejection*

- 5 16. The amendment filed April 14, 2000, is objected to under 35 U.S.C. §132 because it introduces new matter into the disclosure. 35 U.S.C. §132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Claim 97. Applicant is required to cancel the new matter in the reply to this Office Action.

10 *Claim Rejections - 35 USC §112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

15 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

17. Claim 97 is rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

- 20 Claim 97 would describe new matter if it definitely stated a subject matter apparently intended. This is because the specification describes no DNA construct encoding an amino acid sequence that fuses the amino acid at position 199 of the precursor sequence of human protein C to the amino acid at position 212 of the precursor sequence of human protein C. Examples 2-24 of the specification do not suggest such a DNA construct and  
25 Example 15 discloses that the peptide consisting of the amino acids at positions 200-211 of the precursor sequence of human protein C is removed by proteolysis, not by codon deletion within an encoding DNA sequence. It is not clear that a DNA sequence encoding a mammalian Protein C can be altered to permit separate transcription and translation of

the two heavy-chain regions flanking the activation peptide in any environment permitting the resulting polypeptides to independently form a functional, "activated", heavy chain.

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

18. Claim 98 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 98 is indefinite in reciting "The constructed, recombinant **DNA sequence** of claim 97, which **has been activated** to remove amino acids" because the DNA sequence cannot be "activated" to remove the twelve amino acids. There are no amino acids in the DNA sequence. Activation is a proteolytic event mediated, in the case of Protein C and other pro-coagulant and anti-coagulant factors, by a separate protease and cannot be accomplished by altering a DNA sequence, e.g., with codon deletions.

*Claims 93-97 Raise No Issues Under 35 U.S.C. § 112*

19. Claims 93-97 present no issues of enablement or adequate written description under the first paragraph of 35 U.S.C. § 112. Neither do claims 93-97 raise issues of indefinite description under the second paragraph of the statute.

*The Rejection of Claim 83 under 35 U.S.C. § 251 is Withdrawn*

20. The rejection of record of Claim 83 as being an improper recapture of subject matter deliberately cancelled with claims 101 and 102 during prosecution of parent application serial No. 06/699,967 is withdrawn. Applicants cite *In re Clement*, 45 USPQ2d 1161 (Fed. Cir. 1997), and quote a passage spanning pages 1164-65 of the decision to support their position that a narrowing limitation recited in claim 83 "has a material aspect" that is **not** "germane to a prior art rejection". The Federal Circuit panel in *Clement* discussed method claims wherein limitations that had been introduced in response to a rejection over the prior art were removed while other limitations were added. The court more fully

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described the proper analysis where a "reissue claim is broader in some aspects, but narrower in others" thus: "(a) if the reissue claim is as broad as or broader in an aspect germane to a prior art rejection, but narrower in another aspect completely unrelated to the rejection, the recapture rule bars the claim; (b) if the reissue claim is narrower in an aspect germane to prior art rejection, and broader in an aspect unrelated to the rejection, the recapture rule does not bar the claim, but other rejections are possible." 45 USPQ2d at 1165. Claim 83 must fall under the first prong of this analysis because one aspect is as broad as the subject matters of claims 101 and 102 where it describes a "constructed, recombinant DNA sequence that comprises the coding sequence for the active heavy chain of human Protein C" and sets forth the same heavy chain amino acid sequence encoded by a DNA sequence of the cancelled claims 101 and 102.

The further limitation, "the constructed, recombinant DNA sequence of claim 81" recited to narrow the scope of claim 83 cannot, however, be considered to be "narrower in another aspect completely unrelated to the rejection". As Applicants note at page 14 of Paper No. 7, the further limitation of a DNA sequence encoding the light chain is related to the rejection in the parent application where Foster et al. disclose the heavy chain coding sequence but only part of the light chain coding sequence yet was only applied to reject the heavy chain coding sequence. Foster et al. could not then, and cannot now, be applied to reject the further limitation stated in claim 83, thus no impermissible recapture of forfeited subject matter occurs.

*Allowable Subject Matter*

21. Claims 83-97 are ALLOWED because they are free of the prior art of record and subject to no other rejection. Canceling claim 98 and amending the instant specification to correct as much as was corrected by the Certificate of Correction for U.S. Patent No. 4,775,624, will place the instant application in condition for allowance.

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*Conclusion*

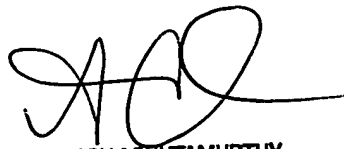
22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

5 A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15 23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is (703) 308-0583. The examiner can be reached Monday through Friday from 9:00 AM to 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. Papers related to this application may be submitted to Group 1800 by facsimile transmission. The faxing of such papers must conform with the notice published November 15, 1989 in the Official Gazette, 1096 OG 30. Informal and unofficial communications may be sent to the Art Unit 1652 FAX number, (703) 308-0294. Official filings should be sent to the Technical Center 1600 FAX number which is (703) 308-4556.

25 24. All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. §122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

35 William W. Moore  
August 4, 2000

  
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